UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

APTARGROUP, INC. Plaintiff, *v.* NEMERA LA VERPILLIERE SAS, NEMERA BUFFALO GROVE LLC, AND NEMERA INSIGHT CHICAGO LLC. Defendants.	Civil Action No. Hon. **JURY TRIAL DEMANDED** [redacted]

COMPLAINT FOR TRADE SECRET MISAPPROPRIATION

Nemera La Verpillière SAS and its U.S. subsidiaries have carried out a months-long campaign to access and misappropriate certain of AptarGroup, Inc.'s trade secrets, including proprietary technologies that are central to the success of Aptar's best-in-class business for bioequivalence testing services. Bioequivalence testing is a key step in a process that is used by pharmaceutical companies to obtain FDA approval of generic pharmaceutical products. Rather than invest in years of research, Nemera accessed Aptar's valuable confidential information about its bioequivalence testing work from an Aptar client who was bound by nondisclosure obligations.

Despite having been caught red-handed, Nemera refuses to even acknowledge the wrongfulness of its conduct. Aptar therefore brings this complaint to recover its trade secret information and stop Nemera from further harming Aptar's interests through use of Aptar's confidential information on current or future projects.

INTRODUCTION

1. AptarGroup, Inc. ("Aptar") is a global leader in the design and manufacturing of a broad range of drug delivery, consumer product dispensing, and active packaging solutions. Aptar creates dosing, dispensing, and protective technologies for the world's leading brands, in turn

making a meaningful difference in the lives, looks, health, and homes of millions of people around the world. Aptar's innovative solutions and services serve a variety of end markets including pharmaceutical, beauty, personal care, home, food, and beverage.

2. Aptar designs and supplies technologies that enable its partners, ranging from large pharmaceutical companies to small biotech startups, to bring to market a variety of medical treatments that are easily administered, often by the patient themselves. These technologies, like nasal drug delivery solutions, are important for pain and cental nervous system crisis conditions requiring fast onset of action therapies.

3. Aptar's Next Breath division specializes in analytical testing of a range of drug delivery systems from early stage to commercialization. Among the services offered by Next Breath is bioequivalence testing that permits manufacturers to establish bioequivalence for a generic intranasally-delivered pharmaceutical, a prerequisite to obtaining regulatory approval and bringing a new generic to market in the United States.

4. As part of its bioequivalence testing services, Next Breath designs and implements plans for *in vitro* bioequivalence ("IVBE") testing of new generic intranasal pharmaceutical products. Designing IVBE test programs is highly complex and time-consuming, requiring validation of the testing prior to conducting studies and involving the selection of dozens of parameters that can interact in unpredictable ways. Through years of research and hands-on experience collaborating with pharmaceutical manufacturers, Next Breath has developed best-in-class know-how about IVBE testing and established itself as the preferred partner of pharmaceutical companies for such testing services.

5. Given the difficulty of developing IVBE test programs and the fact that successful IVBE testing is necessary before a new generic product can be commercially marketed, information

about IVBE testing programs is highly valuable. Next Breath, like other market participants, therefore carefully guards its test design, test validation, test results, and other materials connected to IVBE testing programs as trade secrets.

6. Next Breath provides certain information related to its IVBE testing programs to its clients during the course of designing and executing bioequivalence test studies for the client, including certain details of its proprietary and trade secret test plans, methods, and protocols—all subject to strict nondisclosure agreements. One of those clients is [redacted] which has turned to Next Breath to provide bioequivalence testing services for a new generic intranasal product it is planning to market in the U.S.

7. As part of its work with [redacted], Next Breath provided it with test plans and test results as well as pricing proposals laying out the cost for every aspect of its IVBE testing services. [redacted] was contractually bound to keep this information strictly confidential.

8. [redacted] also conducts business with a would-be competitor of Aptar's, Nemera La Verpillière SAS ("Nemera").

9. Nemera and its U.S. subsidiaries Nemera Insight Chicago LLC ("Nemera Insight") and Nemera Buffalo Grove LLC ("Nemera Buffalo Grove") (collectively the "Nemera Group" or "Defendants") are a French-American conglomerate that, like Aptar and its Next Breath division, works on the design and development of drug delivery devices for the pharmaceutical and generic industries, including bioequivalence testing services for intranasal pharmaceutical products. Unlike Aptar and Next Breath, the Nemera Group has limited experience with bioequivalence testing and lacks both the practical experience and the expert knowledge that Aptar has acquired over years of work and which is crucial to successful test design. As a result of this limited experience and expert

knowledge, the Nemera Group has been unable to compete with Aptar in the market for bioequivalence testing services as long as the playing field has remained level.

10. Faced with this state of affairs, Nemera engaged in a months-long campaign to misappropriate some of Aptar's most valuable trade secrets, including detailed information about the design and results of Next Breath's IVBE test studies. To do so, Nemera utilized its business partner/customer, [redacted], who would act as a conduit for Nemera to acquire Aptar's trade secret information.

11. From at least July through September 2020, a Nemera employee, Géraldine Lebecque, acquired trade secret bioequivalence testing information that belonged to Aptar from her counterpart at [redacted]. Ms. Lebecque did so in part by viewing Next Breath's proprietary materials on screen share and taking screen captures, thereby avoiding the traditional paper trail that would have been generated by email exchange from [redacted] to Nemera.

12. Among the materials Ms. Lebecque obtained were a test plan and a presentation branded "Aptar Pharma," both of which had been prepared strictly for [redacted] use and shared pursuant to confidentiality agreements. The documents included a detailed methodology for one of the most difficult tests required to establish bioequivalence and test results. After obtaining certain of these materials, Ms. Lebecque forwarded them via internal email to several Nemera teammates and fully debriefed them on her videoconference with [redacted]. Ms. Lebecque further stated that she expected her contact at [redacted] to send additional information about another study Aptar had conducted.

13. Ms. Lebecque also obtained at least portions of the detailed pricing proposal for bioequivalence testing services that Aptar had prepared for [redacted] use alone. Nemera

evidently integrated Aptar's pricing information, which is kept secret to protect Aptar's competitive advantage, into the agenda for a meeting about Nemera's bioequivalence testing business.

14. In late September 2020, an Aptar employee inadvertently received via carbon copy two emails between Ms. Lebecque and her counterpart at [redacted] which laid bare Nemera's ongoing activities. Immediately after Nemera's conduct came to light, Aptar began an investigation into Nemera's acts.

15. It is already clear from just Aptar's preliminary findings that Nemera has been accessing, receiving, disclosing, and using Aptar's trade secrets on an ongoing basis to Aptar's direct detriment in order to harm Aptar in the marketplace. Aptar therefore brings this suit to enjoin Nemera's misappropriation of Aptar's trade secrets and recover for the damage Nemera is causing.

PARTIES

16. Plaintiff AptarGroup, Inc. ("Aptar") is a Delaware corporation, with its principal place of business at 265 Exchange Drive, Suite 100, Crystal Lake, Illinois 60014. Aptar is a leading global provider of a broad range of innovative dispensing and sealing solutions in the food and beverage, beauty and home, and pharmaceutical markets. Aptar has 48 manufacturing facilities in North America, Europe, Asia, and South America, and nearly 13,000 employees.

17. Defendant Nemera La Verpillière SAS ("Nemera") is a French company, with its principal place of business in La Verpillière, France. Nemera, together with its U.S. subsidiaries, designs and manufacturers drug devices and related products and services globally, including in the United States. It operates four manufacturing facilities globally, including one in Buffalo Grove, Illinois.

18. Nemera Insight Chicago LLC ("Nemera Insight") is a Delaware limited liability company, with its principal place of business at 4660 North Ravenswood Avenue, Chicago, Illinois 60640. On information and belief, Nemera Insight is a wholly owned subsidiary of Nemera US Holding Inc. ("Nemera US Holding"), which in turn is wholly owned by Nemera.

19. Nemera Buffalo Grove LLC ("Nemera Buffalo Grove") is a Delaware limited liability company, with its principal place of business at 600 Deerfield Parkway, Buffalo Grove, Illinois 60689. On information and belief, Nemera Buffalo Grove is a wholly owned subsidiary of Nemera US Holding.

JURISDICTION

A. Subject Matter Jurisdiction

20. This Court has subject matter jurisdiction pursuant to 18 U.S.C. § 1836(c).

21. In addition, the Court has jurisdiction based on general federal question jurisdiction, 28 U.S.C. § 1331.

B. Personal Jurisdiction

1. Nemera's U.S. presence

22. Nemera exercises complete control over the actions of each of its U.S. subsidiaries. Nemera and its U.S. subsidiaries hold themselves out to the public as a single entity, without any distinction in operations or corporate form.

23. Marc Hamel is the Chief Executive Officer of Nemera, Nemera US Holding, and Nemera Buffalo Grove. According to its filings with the Illinois Secretary of State, Nemera Insight's sole manager is Nemera US Holding (of which Mr. Hamel is CEO).

24. Nemera and its U.S. subsidiaries (together, "the Nemera Group") jointly use a single website, www.nemera.net. That website describes the business of "Nemera" as a single entity, with no distinction between Nemera and its U.S. subsidiaries.[1]

25. Nemera advertises its number of employees (2,100) and manufacturing "plants in Europe and the USA" (four) without distinguishing between itself and any of its U.S. subsidiaries.[2] It likewise purports to abide by one corporate code of conduct and one code of conduct for "Nemera

[1] *About Us*, Nemera, https://www.nemera.net/about-us (last accessed Feb. 16, 2021).

[2] *Manufacturing Quality*, Nemera, https://www.nemera.net/manufacturing-quality (last accessed Feb. 16, 2021).

suppliers" without any distinction between itself and its U.S. subsidiaries.[3] Nemera advertises open jobs in Germany, France, and the United States, touting the benefits of "[e]very job at Nemera," without distinguishing between Nemera or its U.S. subsidiaries.[4]

26. Nemera promotes itself as a market leader in the development of ophthalmic, nasal, dermal, parenteral, and inhalation drug delivery devices, again without any distinction between its operations and those of its U.S. subsidiaries, including on its website and in social media.

27. The Nemera Group manufactures these products in both Europe and the United States. Its U.S. manufacturing takes place at its facility in Buffalo Grove, Illinois. It claims to employ the same manufacturing and quality control practices at its Buffalo Grove facility as it does at its French and German facilities.[5]

28. The Nemera Group also sells these products in both European and U.S. markets, including in Illinois, without any visible distinction between what is manufactured, marketed, or sold by Nemera and what is manufactured, marketed, or sold by its U.S. subsidiaries. For instance, in 2015, the U.S. Food and Drug Administration ("FDA") approved a single 510(k) application[6] for a type of syringe called the "Safe'n'Sound Stacked Passive Delivery System."[7] The FDA description of the 510(k) notification lists "Nemera," without any further elaboration, as the "applicant" and as a

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[3] *Nemera Group Code of Conduct*, Nemera, https://secureservercdn.net/160.153.138.177/369.861.myftpupload.com/wp-content/uploads/Nemera-Code-of-Conduct-EN.pdf?time=1582204895 (last accessed Feb. 16, 2021); *Supplier Code of Conduct*, Nemera, https://www.nemera.net/about-us/supplier-code-conduct (last accessed Feb. 16, 2021).

[4] *Careers*, Nemera, https://fa-emia-saasfaprod1.fa.ocs.oraclecloud.com/hcmUI/CandidateExperience/en/sites/CX_1001 (last accessed Feb. 16, 2021).

[5] These include rotary and linear high speed assembly, ultrasonic welding and gluing, automatic packing, the same standard validation process, metro-tomography, tactile and optical 3D measurement system, tight tolerance and micro molding, multi shot molding, stack molds, and in process control using in mold sensors.

[6] A 510(k) is a premarket application made to the FDA to demonstrate that a device is safe, effective, and substantially equivalent to a legally marketed device. *Premarket Notification 510(k)*, U.S. FDA, https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k (Mar. 13, 2020).

[7] *510(k) Premarket Notification: K150562*, U.S. FDA, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K150562 (last updated Jan. 25, 2021).

"correspondent," with no explanation as to whether the applicant or correspondent was Nemera itself or one of its U.S. subsidiaries. The description also lists one contact address at 600 Deerfield Parkway, Buffalo Grove, Illinois 60089—the site of Nemera's Buffalo Grove manufacturing facility—and one contact address in La Verpillière, France—the site of Nemera's headquarters.

29. Similarly, the FDA letter approving the 510(k) premarket notification was addressed to Beatrice Grand Demars, a regulatory compliance manager in La Verpillière, France. The same letter later on listed the address for "Nemera" as the Buffalo Grove address.[8]

30. Product development for both Nemera and its U.S. subsidiaries is run at least in part through Nemera's "Insight Innovation Center," which Nemera describes as a "cross-disciplinary team of 150 passionate and dedicated innovation experts, with offices in La Verpillière, France and Chicago, IL."[9]

31. The Insight Innovation Center was founded in 2019 after Nemera, through Nemera US Holding, acquired a Chicago-based consulting firm called Insight Product Development. Nemera targeted Insight Product Development because of its capabilities "in both medical and drug delivery services spanning the full development life cycle from early user research and human factors through to verification and design transfer."[10] The new Insight Innovation Center resulted from "[t]he combination" of the Chicago-based organization with "Nemera's well established design center in La Verpillière (France)."[11]

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[8] June 2, 2015 Letter from E. Keith to B. Grand Demars, https://www.accessdata.fda.gov/cdrh_docs/pdf15/K150562.pdf.

[9] *Insight Innovation Center*, Nemera, https://www.nemera.net/innovation-development (last accessed Feb. 16, 2021).

[10] *Nemera Acquires Insight Product Development to Strengthen Its Capabilities in Early Stage Development and to Reinforce Client Proximity in North America*, Nemera, https://www.nemera.net/wp-content/uploads/2019/08/NEMERA_PR-Acquisition-Insight-PD_08082019.pdf (Aug. 8, 2019).

[11] *Id.*

32. Nemera launched the Chicago- and France-based Insight Innovation Center in large part to create "a strong development footprint in North America and significantly improve[] proximity to North America based customers."[12]

33. Prior to its acquisition, Insight Product Development was located at 4660 North Ravenswood Avenue, Chicago, Illinois 60640. Following Nemera's acquisition of Insight Product Development, Nemera Insight Chicago was formed as a limited liability company, with its principal place of business also located at 4660 North Ravenswood Avenue, Chicago, Illinois 60640.[13] On information and belief, Nemera Insight Chicago is the corporate name housing what used to be Insight Product Development.

34. However, Nemera's Insight Innovation Center is not limited to the former operations of Insight Product Development or wholly housed within Nemera Insight Chicago. Rather, the Nemera Group has delivered on its stated goal of "combining" the former Insight Product Development with Nemera's preexisting design center in La Verpillière, France to create a single "Innovation Center" jointly headquartered in Chicago and in France.

35. For instance, Nemera's website describes the Insight Innovation Center as a single entity that employs 150 "innovation experts" in offices in both Chicago, Illinois and La Verpillière, France.[14] These experts work in Chicago and France to fulfill Nemera's research and design needs, purportedly by identifying product and design opportunities, testing prototypes, launching and then scaling pilot projects to fully test new products, and ultimately bring those products to market in both Europe and the United States.[15]

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[12] *Id.*

[13] *Corporation / LLC Search / Certificate of Good Standing: Nemera Insight Chicago LLC*, Ill. Sec'y of State, https://apps.ilsos.gov/corporatellc/CorporateLlcController (last accessed Feb. 16, 2021).

[14] *Insight Innovation Center*, Nemera, https://www.nemera.net/innovation-development (last accessed Feb. 16, 2021).

[15] *Id.*

2. Nemera's U.S. contacts underlying this dispute

36. Nemera and its U.S. subsidiaries develop, manufacture, market, and sell products in the United States that are in direct competition with Aptar's products. Like Aptar, the Nemera Group is particularly active in developing, manufacturing, and marketing nasal spray drug delivery systems. The Nemera Group has established a "Drug Equivalence Program," that is specifically designed to boost marketing of its standard and custom nasal spray products.[16] It manufactures and markets standard nasal spray pumps as well as customized nasal spray devices based on client needs for U.S. and international distribution.[17]

37. The Nemera Group regularly promotes its products, including its nasal spray products, at U.S.-based trade conferences. For instance, the Nemera Group was a sponsor and exhibitor at the 2018 Respiratory Drug Delivery ("RDD") conference in Tucson, Arizona.[18]

38. The Nemera Group markets its nasal spray products in part based on its products' and services' compliance with U.S. FDA guidance and draft guidelines, which it describes as "the most detailed and stringent regulation compared to the approved European and Brazilian regulations."[19] Its adherence to FDA guidelines underpins its marketing of nasal spray products in both the United States and elsewhere.

39. As described below in Part G, the Aptar trade secrets at issue in this dispute relate to bioequivalence testing for nasal spray products, such as those the Nemera Group manufactures,

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[16] *Bioequivalence for Nasal Sprays: Importance of Device Performance*, Nemera, https://secureservercdn.net/160.153.138.177/369.861.myftpupload.com/wp-content/uploads/2018/04/WP-BIOEQUIVALENCE-NASAL-SPRAY.pdf (last accessed Feb. 16, 2021).

[17] *Id.*

[18] Nemera has repeatedly presented at U.S.-based trade and research conferences in recent years, including in Boston, California, and Arizona.

[19] *Bioequivalence for Nasal Sprays: Importance of Device Performance*, Nemera, https://secureservercdn.net/160.153.138.177/369.861.myftpupload.com/wp-content/uploads/2018/04/WP-BIOEQUIVALENCE-NASAL-SPRAY.pdf (last accessed Feb. 16, 2021).

markets, and distributes in the United States and elsewhere. On information and belief, employees with Nemera Insight Innovation Center will use (or have already used) Aptar's trade secrets to test, develop, market, and distribute nasal spray products in the United States and elsewhere.

40. Alain Regard, one of the Nemera Group employees who received Aptar's trade secrets, is a Technology Product Manager situated within Nemera's Chicago- and France-based Insight Innovation Center. *See infra*, Factual Allegations: Part G.

41. As a Technology Product Manager with the Insight Innovation Center, Mr. Regard is responsible for innovation and early-stage product development in the field of nasal drug delivery.[20] Mr. Regard works as part of the Chicago- and France-based Insight Innovation Center to develop and market nasal drug delivery devices and systems for the United States and European markets.

42. Mr. Regard is actively involved in the Nemera Group's U.S.-based marketing efforts, including in connection with offering IVBE services. On several occasions, he has promoted Nemera products and Nemera-sponsored research in the U.S. market, including in the nasal spray space. He presented a Nemera-sponsored poster at the RDD's 2020 annual conference held in April and June 2020. The conference was scheduled to be held in Desert Springs, California but was instead conducted online due to the COVID-19 pandemic, brought together device and equipment designers such as the Nemera Group and Aptar with U.S.-based and international customers and suppliers. Mr. Regard has also presented in person at other trade conferences in the U.S.

43. At the 2020 RDD conference, Mr. Regard presented a Nemera-sponsored poster relating to nasal aerosol delivery. In 2018, Mr. Regard also presented a paper on nasal drug delivery at the RDD conference in Tucson, Arizona.

[20] *Alain Regard*, The Aerosol Soc'y, https://aerosol-soc.com/speakers/alain-regard (last accessed Feb. 16, 2021).

44. Céline Petitcolas, another one of the Nemera Group employees to whom Aptar's trade secrets were disclosed, also works with Nemera's Chicago- and France-based Insight Innovation Center. *See infra*, Factual Allegations: Part G. Like Mr. Regard, she is actively involved in promoting Nemera research and product development in the U.S. market. She presented a paper at the 2020 RDD entitled "An Alternative Statistical Method to Assess In Vitro Bioequivalence of Nasal Products."

45. In order to enable Mr. Regard and Ms. Petitcolas to present posters at the RDD conferences, the Nemera Group was obligated to sponsor those conferences. On information and belief, the Nemera Group sponsors U.S.-based conferences such as the RDD conference and pays for employees such as Mr. Regard and Ms. Petitcolas to present at them so as to market its products to U.S.-based customers.

46. Ms. Petitcolas recently co-authored an article entitled "Between-Batch Bioequivalence (BBE): A Statistical Test to Evaluate *In Vitro* Bioequivalence Considering the Between-Batch Variability."[21] The article, which was published in the U.S.-based journal of the American Association of Pharmaceutical Scientists, describes techniques for estimating bioequivalence in the development of generic drugs, with a focus on nasal sprays and spray pattern—the subject of Aptar's misappropriated trade secrets. The article was published in September 2020, following certain of the acts of misappropriation at issue in this case.

47. On information and belief, the reason Aptar's misappropriated information was shared with Mr. Regard and Ms. Petitcolas as well as other Nemera Group employees was because

[21] J. Bodin, et al., *Between-Batch Bioequivalence (BBE): A Statistical Test to Evaluate* In Vitro *Bioequivalence Considering the Between-Batch Variability*, 22 AAPS J. 119 (2020), https://www.nemera.net/wp-content/uploads/2009-Article_Between-BatchBioequivalenceBBE.pdf.

of their role in researching and developing bioequivalence testing for nasal sprays and marketing related products in the U.S. and other markets.

C. Venue

48. Venue is proper in this district under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to Aptar's claims occurred in this district through the actions of the Nemera Insight Innovation Center, the Nemera division responsible for developing and marketing new products, which operates in Chicago, Illinois.

49. In the alternative, venue is proper in this district because Defendants are all subject to the court's personal jurisdiction with respect to this action.

FACTUAL ALLEGATIONS

A. Aptar's Expertise in IVBE Testing

50. The process of obtaining the regulatory approvals necessary to market pharmaceutical nasal spray products is costly and time-consuming.

51. In the case of new generic versions of nasal spray products, the process involves demonstrating that the generic product's drug delivery system is bioequivalent to the already approved brand name product through the submission of an abbreviated new drug application ("ANDA") to the FDA. Under the Food, Drug, and Cosmetic Act, a "drug shall be considered to be bioequivalent to a listed drug if—(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or (ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug." 21 U.S.C. § 355(j)(8)(B).

52. The demonstration of bioequivalence is based, in part, on *in vitro* bioequivalence ("IVBE") test results.

53. Prior to obtaining IVBE test results for ANDA submissions for nasal spray products, IVBE test protocols must be developed and validated, a process that can take many years.

54. Without a successful IVBE program to develop and validate test designs and protocols, a manufacturer of a new generic nasal spray product would need to spend years to develop and validate its own IVBE testing.

55. Over the last twenty years and drawing on the knowledge and experience of its scientists, Aptar developed an IVBE testing program for the development and validation of IVBE testing that can be used to obtain FDA approval of generic nasal spray products.

56. Aptar's IVBE testing program permits manufacturers of nasal generic spray products to quickly conduct IVBE testing that is required to submit an ANDA for regulatory approval. This is critical to the commercial success of generic nasal spray products as the first product to come to market will benefit from a significant commercial advantage. For instance, the first generic product applicant to file a substantially complete ANDA meeting certain requirements will be eligible for a 180-day period of exclusivity as to other ANDA applicants. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb).

57. Through years of work and the investment of significant resources, Aptar, and in particular its Next Breath division, has become the industry leader in developing, validating, and executing IVBE testing to demonstrate bioequivalence of generic nasal spray products.

58. Using the latest instrumentation and methodologies, and drawing on its extensive experience, Aptar develops specific programs for its clients to meet all requirements necessary for IVBE testing.

59. Aptar has a proven track record of working with regulatory agencies to obtain bioequivalence approval, including in the United States, Europe, Canada, India, and the Americas.

60. Since the inception of Aptar's Next Breath division, the company has collaborated with over sixty-five pharmaceutical companies and has contributed towards successful regulatory

submissions in domestic and international markets. Aptar's expertise and results have been used in many ANDA's as well as new drug applications ("NDA's"), 510(k) studies, biologics license applications ("BLA's"), and abbreviated biologics license applications ("aBLA's") submitted to the FDA.

B. Aptar's Development of Its Proprietary IVBE Test Program

61. Demonstrating the *in vitro* bioequivalence of a nasal spray product is required to obtain FDA approval for the product, without which a company cannot commercially market and sell that product.

62. Bioequivalence for locally acting drugs delivered by nasal aerosol and nasal spray is usually characterized using the following tests: (1) Single Actuation Content Through Container Life; (2) Droplet Size Distribution by Laser Diffraction; (3) Drug in Small Particles/Droplets or Particle/Droplet Size Distribution by Cascade Impactor; (4) Spray Pattern; (5) Plume Geometry; and (6) Priming and Repriming.

63. Each of the tests are validated prior to conducting the study, consistent with the FDA guidance recommending validation of "all in vitro tests for accuracy and precision prior to the study" such as validation of the analytical methods used for analysis of the samples from the *in vitro* tests.[22]

64. Test design and validation is time-consuming and requires know-how as to the particular testing that is being done. In addition to validation, IVBE testing requires the selection of parameters that, when changed, may affect the results of the test. For example, the initial values for each test parameter, as well as the subsequent changes in the values, must be carefully selected for the test to be successful.

65. When designing a testing program for a client's new generic nasal spray product, Aptar validates the testing and determines the initial values based on its know-how for the various

[22] Ctr. for Drug Evaluation & Res., Food & Drug Admin., *Guidance for Industry: Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action* 10 (Apr. 2003), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bioavailability-and-bioequivalence-studies-nasal-aerosols-and-nasal-sprays-local-action.

parameters. As the test methods are developed, Aptar then will typically adjust those parameters to refine the testing by drawing on its deep experience in the field.

66. Aptar works collaboratively with its clients on the entire IVBE testing process for their new generic nasal spray product. As part of this process, Aptar prepares for its clients a method development report that tracks the development of the testing over time as well as validation and, ultimately, a final written report detailing the testing and validation of the tests.

67. One of the principal purposes of these reports is to provide a complete record of the parameters necessary to meet FDA regulatory expectations and duplicate the test methods developed, validated, and ultimately executed by Aptar during testing.

68. If a competitor gained access to Aptar's method development report, final written report, or other documentation such as its study protocol, test method, or validation report, it would have a blueprint of Aptar's work, allowing the competitor to short circuit the hard labor of developing and validating test methods and immediately obtain know-how that Aptar has built over years of work.

69. Each of these aspects of an IVBE test study, including the study protocol as well as the final test plan, incorporates Aptar's unique and proprietary know-how. In addition, each of them is essential to completing a successful IVBE test study and establishing bioequivalence for a new drug and therefore would be extremely valuable to a competitor on its own.

C. Aptar's Protection of Its Trade Secrets

70. Because of the sensitive and valuable nature of its work product related to IVBE testing, including test methods, method development reports, validation reports, and final bioequivalence reports, Aptar rightly regards this work product and underlying information as trade secrets.

71. Aptar derives a significant economic benefit from keeping its proprietary work product connected to IVBE testing secret, such that Aptar can offer services that its competitors cannot.

72. If one of Aptar's competitors gained access to this work product, the competitor would gain a significant competitive advantage.

73. Accordingly, Aptar makes significant efforts to protect access to the work product and information.

74. Access to confidential trade secret information within Aptar is restricted to designated personnel on a "need to know" basis. Aptar's employees sign a confidentiality agreement and code of conduct agreeing to maintain the confidentiality of all information entrusted to them by Aptar or by its suppliers and customers before any confidential trade secret information is disclosed to the employees. Aptar aggressively polices compliance with employee confidentiality obligations, even to the point of bringing suit to enforce such obligations.

75. Aptar also requires contractors, consultants, vendors, and manufacturers to sign confidentiality agreements before any confidential trade secret information is disclosed to them.

76. Databases hosting Aptar's confidential information require passwords and dual-authentication or multi-factor authentication for remote access. In addition, Aptar restricts and controls physical access to its facilities.

77. Aptar requires customers to enter into formal agreements that include confidentiality provisions before Aptar provides them with confidential trade secret information (including its proprietary test methods).

78. To the extent that the results of certain materials created by Aptar related to IVBE testing are submitted to the FDA when an Aptar client seeks regulatory approval for its product, the submission of such results does not mean that Aptar's know-how in designing and validating those test results enters the public domain. For example, pre-study validation and the know-how used to determine and select certain parameters would not be submitted to FDA. And the FDA provides protections to prevent the disclosure of test protocols if they constitute trade secrets or confidential commercial information.

79. Aptar's treatment of its work product connected to IVBE testing is consistent with industry practice. The few companies that offer IVBE test services keep their methodologies and test results strictly confidential, and market participants are aware of this general practice.

D. Aptar's Collaboration with [redacted]

80. In 2017, Aptar France SAS ("Aptar France"), a French indirect subsidiary of Aptar, was retained by [redacted], a French pharmaceutical company, to collaborate on the development of a new generic version of a nasal drug product. Specifically, [redacted] was attempting to create a product for intranasal delivery of [redacted]. At the time, no generic version of [redacted] was approved for sale in the U.S., and the first company to complete IVBE testing and gain regulatory clearance for its generic stood to reap a lucrative financial reward.

81. To support its efforts to gain regulatory approval for its [redacted] product, [redacted] engaged Aptar's Next Breath division to develop test methods for spray pattern testing as well as single actuation content uniformity, droplet size distribution, plume geometry, and amount of drug in small particles testing; validate the test methods for repeatability, immediate precision, and robustness; and ultimately use the test methods to perform IVBE studies of the product.

82. Developing and executing methods for the IVBE testing of [redacted]'s [redacted] product was at the core of Aptar and its subsidiary's work for [redacted].

83. [redacted] decision to engage Aptar to design and execute the IVBE tests was consistent with its general practice of outsourcing such work, as [redacted] does not develop or conduct bioequivalence studies itself. [redacted] entirely lacked the experience or knowledge necessary to develop successful methods for the IVBE testing of its [redacted] product.

84. By turning to Next Breath to develop IVBE test methods, [redacted] benefitted from the company's deep experience with IVBE testing and gained a significant competitive edge.

85. Aptar France and [redacted]'s relationship was governed by a series of confidential disclosure agreements designed to protect the parties' confidential information: [redacted]

[redacted]

E. Aptar's Proprietary Work Product from the [redacted] Collaboration

1. Aptar's test methods and results

86. Aptar's Next Breath division provided highly confidential materials containing trade secret information about Aptar's IVBE testing program to [redacted] as part of its work on the [redacted] product.

87. The confidential materials provided by Aptar included the IVBE test program the company had created for spray pattern testing of the [redacted] product, including method development reports, study protocols, test methods, validation reports, and bioequivalence reports.

88. Of the tests conducted as part of an IVBE test study, the spray pattern test is perhaps the most difficult to design and validate. The spray pattern test involves actuation (i.e., operation) of the product's pump with a camera directed at the spray output. There are at least twelve parameters that affect the results of a spray pattern test.

89. One document Aptar shared with [redacted] titled "Test Plan #02" and provided in late May 2020, memorialized a test plan to investigate spray pattern method parameters for the product following failed bioequivalence. The document included a table [redacted]

90. Additional tables and charts in the "Test Plan #02" document made clear [redacted]

91. Another document Aptar provided to [redacted], a PowerPoint presentation titled "NB [redacted] IVBE," presented detailed results of Aptar's application of its [redacted] to the

[redacted]product and confirmed that Test Plan #02 was successful. The presentation was provided by Aptar to [redacted] on June 25, 2020.

92. Aptar's methodologies and information contained in the "Test Plan #02" and "NB [redacted]IVBE" documents are not public, and Aptar rightly regards these materials as its trade secrets.

93. Aptar provided the "Test Plan #02" and "NB [redacted] IVBE" documents to [redacted] solely in furtherance of its work on the [redacted]product. Aptar did so pursuant to its confidentiality agreements with [redacted]and with the understanding that [redacted] would maintain the secrecy of Aptar's materials. For example, the materials in the two documents relate to [redacted], which was a subject of the companies' [redacted] and their [redacted]

2. Aptar's pricing information

94. In the course of its work on the [redacted] product, Aptar and its subsidiaries submitted invoices to [redacted] for payment.

95. On May 12, 2020, Aptar France submitted two invoices billed to [redacted] a subsidiary of [redacted] The first, dated April 29, 2020, set out the price Aptar charged for analytical services for a "combination product," which the cover email makes clear was the [redacted] product. The invoice further stated that [redacted]was to "keep absolutely confidential the information of any kind provided verbally, in writing, or in any other form or which it may become aware in negotiating or executing Orders of Products." The second invoice, dated April 10, 2020 invoice, set out the price Aptar charged for another portion of its work on the [redacted] product.

96. Aptar and its subsidiaries also provided to [redacted] pricing proposals to design and execute IVBE testing of other nasal drug products.

97. In early 2019, Next Breath submitted to [redacted] a pricing proposal for work on IVBE testing of a [redacted] nasal drug product.

98. The proposal laid out in detail the prices Aptar would charge for every aspect of the IVBE testing process, from project set-up and materials to development and validation of the test methods and, ultimately, the actual testing and creation of a final report.

99. The prices Aptar charges for its IVBE test work, such as the prices included on the invoices and pricing proposal Aptar provided to [redacted] are not generally known or readily ascertainable. (For example, Aptar does not provide detailed price breakdowns in response to general, non-confidential inquiries.) Aptar rightly regards information about the costs of its services as a trade secret.

100. Aptar derives economic value from keeping secret its proprietary pricing information. Among other reasons, doing so prevents competitors from undercutting Aptar on price. Aptar therefore keeps its pricing information strictly confidential.

101. Aptar's treatment of its pricing information is consistent with industry practice. The small number of companies that provide IVBE testing services keep their prices confidential, and market participants are aware of this general practice.

102. Aptar provided the invoices and pricing proposal to [redacted] solely for the purpose of conducting business with [redacted] Aptar did so pursuant to the parties' confidentiality agreements and with the understanding that [redacted] would keep the materials secret. For example, the pricing proposal was for work on a [redacted] product, which was a subject of the companies' [redacted]

F. Nemera

103. [redacted] also conducts business with companies other than Aptar that offer IVBE testing services, including Nemera.

104. [redacted] work with such companies is entirely unconnected to its work with Aptar. Aptar does not partner with other laboratories that offer IVBE testing services and, as laid out in its confidentiality agreements with clients like [redacted] does not allow clients to share its confidential work product related to IVBE testing with other laboratories like Nemera.

105. Nemera is a relative newcomer to the market for IVBE testing for nasal drug products. It has far less experience than Aptar designing methods for IVBE tests and lacks the first-in-class know-how that Aptar has built up over years of work.

106. It would take years for Nemera to gain the know-how and expertise that Aptar has developed, if Nemera were able to do so at all.

107. Because Aptar has expertise designing and executing IVBE test methods which Nemera lacks, Aptar enjoys a competitive edge over Nemera.

108. Nemera is actively seeking to grow its business for IVBE test services for nasal drug products and is a direct competitor of Aptar in that market.

109. If Nemera were to gain access to Aptar's trade secret work product on IVBE testing, Nemera would immediately gain a significant competitive advantage, to Aptar's direct detriment.

110. If Nemera were to gain access to pricing information for Aptar's services, Nemera would immediately gain a competitive advantage, including the ability to specifically undercut Aptar on price, to Aptar's direct detriment.

111. Next Breath has never provided, nor would it ever provide, its work product to Nemera.

G. Nemera's Appropriation of Aptar's Trade Secret Materials

112. On information and belief, [redacted] engaged Nemera to conduct IVBE testing for a product it is developing.

113. At least one of the [redacted] employees who worked directly with Next Breath on the IVBE testing services Next Breath was providing for [redacted] product also worked with Nemera. Specifically, [redacted], a development project manager at [redacted] and Aptar's direct contact on the [redacted] product, worked with a program manager at Nemera, Géraldine Lebecque, who is involved with Nemera's IVBE testing services business.

1. Aptar's test methods and results

114. On July 30, 2020, Ms. Lebecque held a videoconference with Ms. [redacted].

115. The purpose of the videoconference is unclear. What is now clear, though, is that during the course of the videoconference, [redacted] provided to Ms. Lebecque Aptar's "NB [redacted] IVBE" presentation via screen-share.

116. In doing so, [redacted] failed to keep the Next Breath information secret as required by numerous confidentiality agreements between [redacted] and Aptar.

117. Rather than stop the screen share, Ms. Lebecque captured at least two screenshots of the presentation, including Slide 18, which had a table, chart, and commentary laying out in detail the results of tests Aptar conducted pursuant to its proprietary [redacted] method described above, and portions of Slide 20, which had a chart detailing additional results from the tests. One screenshot also included thumbnails of six additional slides. Each slide was clearly branded with the name "Aptar Pharma."

118. Ms. Lebecque did not receive the materials via email, which would have created a paper trail. Rather, she retained the materials by taking screenshots during the videoconference.

119. Later that day, Ms. Lebecque shared with her teammates via email the information she had gleaned from the videoconference. That email included the two screenshots Ms. Lebecque had captured during the videoconference along with an explanation of the import of the materials. Ms. Lebecque further noted that [redacted] was to send additional slides about another study "they" had conducted. (English translation.) Céline Petitcolas and Alain Regard of Nemera's Chicago- and France-based Innovation Center were among the recipients of the email.

120. Ms. Lebecque's email indicates that she had been fully debriefed on Aptar's ongoing work, including that [redacted] (the results of which Ms. Lebecque laid out) and that [redacted] (English translation.)

121. From context, it is clear that "they" referred to the party that had created the materials Ms. Lebecque was now sharing with her team, which she knew to be Aptar.

122. Then, on September 25, 2020, Ms. Lebecque received an email with portions of Aptar's "NB [redacted] IVBE" presentation and "Test Plan #02" document from [redacted] These materials once again included the table and chart from Slide 18 and the chart from Slide 20. Crucially, this email also included the table from the "Test Plan #02" document which provided full

details of how to execute Aptar's [redacted] method. The email also had [redacted] commentary on Aptar's test method and the results of its tests.

123. Five minutes later, Ms. Lebecque received another email from [redacted] with additional commentary on Aptar's materials.

124. Again, Ms. Lebecque only received screenshots of portions of the documents in the body of the email, rather than the documents in full as attachments.

125. And again, Ms. Lebecque would have known that the materials she received from [redacted] in the two emails were obtained from Aptar. Ms. Lebecque was already aware that the materials excerpted from Slides 18 and 20 came from Aptar thanks to the videoconference, and given that those slides clearly showed the results of a [redacted] test, the logical conclusion is that the table with the [redacted] method itself also came from Aptar. (The table originally had Next Breath's name and logo directly above it, but this had been cropped out before it was sent.) Ms. Lebecque also would have known the materials could not have come from [redacted] given that [redacted] does not design or carry out IVBE tests, and that Aptar was the most likely candidate to have generated the materials.

126. Upon information and belief, Nemera obtained Aptar's confidential materials because Nemera's IVBE testing work for [redacted] on a different nasal product [redacted] had been developing had not been successful. This information was being provided to Nemera so that they could accelerate their project.

127. Ms. Lebecque's actions demonstrate that she was also aware of the sensitive nature of the materials she received during the videoconference and in the September 25, 2020 emails. In her post-videoconference debrief to her teammates, Ms. Lebecque referred to the data she had received as the results of a "competing" study. (English translation.) In addition, after receiving the September 25 emails, Ms. Lebecque immediately alerted [redacted] that the latter had accidentally copied an employee of Nemera's competitor (namely, Aptar) on the emails and suggested she attempt to recall the message, presumably so that Aptar would not learn of the communication.

128. The emails indicate that Nemera intended to use Aptar's trade secret information in its own work. For example, [redacted] email stated that in implementing Aptar's method, Nemera could decrease the number of units tested and set the number of sprays as it wished.

129. Ms. Lebecque knew, or had reason to know, that [redacted] had a duty to Aptar to keep the materials secret. Participants in the market for IVBE testing services are aware that industry practice is to keep IVBE test methods and results confidential. Moreover, Ms. Lebecque only received excerpts of the "NB [redacted] IVBE" and "Test Plan #02" documents and, initially, only via screen-share. This back-alley manner of operating indicates that Ms. Lebecque was aware that the materials were not [redacted] to share, or, alternatively, would have given Ms. Lebecque reason to conclude that the materials were not [redacted] to share.

2. Aptar's pricing information

130. On June 11, 2020, several Nemera employees received an email from [redacted] which in turn attached two other emails. One of the attached emails contained a portion of Aptar's detailed pricing proposal to [redacted] for work on IVBE testing and for Aptar materials. Every page of Aptar's proposal stated that "This proposal is for the confidential use of Next Breath and [redacted]. Its distribution to third parties is expressly prohibited without the written consent of the other." Aptar never provided [redacted] consent to distribute the proposal to Nemera.

131. While Nemera has refused to produce the parent email (or even its subject line), the complete version of the attached email with the pricing proposal, or the second attached email at all, context suggests that Nemera intended to use Aptar's pricing proposal for competitive purposes. The subject of the attached email with the pricing proposal, "Agenda Bioeq - Meeting 12/12 in Paris," indicates Nemera intended to make use of its competitor's pricing at a meeting about its bioequivalence (i.e., IVBE) program. (English translation.)

132. On July 30, 2020, a Nemera employee received two more emails from [redacted] which attached the April 10 and April 29, 2020 invoices itemizing Aptar's prices for certain of its IVBE testing services. That employee was Céline Petitcolas of the Chicago- and France-based

Nemera Innovation Center. On August 4, 2020, Ms. Petitcolas once again received an email from [redacted] with the April 10, 2020 invoice.

133. The Nemera employees who received the emails would have known that the materials had been obtained from Aptar. The invoices are plainly marked with Aptar's name. As for the email with Aptar's pricing information, it is not possible to determine whether Aptar was explicitly identified as the source, since Nemera has refused to provide the email. However, Nemera's employees would have known that, by definition, the pricing proposal had been created for [redacted] by a third party, which Nemera would have known to be Aptar.

134. The Nemera employees who received the emails (including Adrien Tisserand, a key account manager who was a recipient of the email with Aptar's pricing proposal) knew, or had reason to know, that [redacted] had a duty to Aptar to keep its pricing information secret. Participants in the market for IVBE testing services are aware that industry practice is to keep pricing confidential.

135. Nemera resorted to illicitly procuring Aptar's trade secret test methods, test results, and pricing information through [redacted], despite [redacted] being bound by confidentiality agreements, because Nemera recognized that the information was valuable and was unable to develop or obtain it fairly. In acquiring, disclosing, and using Aptar's trade secrets, Nemera misappropriated Aptar's trade secrets.

COUNT I: Violation of Federal Defend Trade Secrets Act, 18 U.S.C. § 1836

136. Aptar incorporates all of the above paragraphs as if fully restated herein.

137. Aptar owns and possesses certain confidential, proprietary, and trade secret information, including scientific, technical, and engineering information and financial, business, and economic information, as alleged above.

138. Aptar's trade secrets are reflected in the test methods, test results, and pricing information received by Defendants as described above. Various aspects of the materials Defendants received constitute Aptar's trade secrets. Examples of Aptar's trade secret information

include its proprietary [redacted] method for selecting appropriate values for certain parameters of the spray pattern test for a [redacted] nasal drug product, the results of such tests, and the prices Aptar charges for its services.

139. Aptar's confidential, proprietary, and trade secret information relates to products used in, or intended for use in, interstate or foreign commerce.

140. Aptar has taken reasonable measures to keep such information secret, as alleged above. These measures include only permitting employees to access confidential trade secret information on a "need to know basis"; requiring employees, contractors, consultants, vendors, manufacturers, and customers to sign confidentiality agreements before confidential trade secret information is disclosed to them; protecting confidential trade secret information with passwords (and dual authentication or multi-factor authentication for remote access); and restricting and controlling physical access to its facilities.

141. Aptar's confidential, proprietary, and trade secret information derives independent economic value from not being generally known to, and not being readily ascertainable through proper means by, another person who could obtain economic value from the disclosure or use of the information. Aptar's confidential, proprietary, and trade secret information is developed by Aptar for its own use and is not available to Aptar's competitors.

142. Aptar's confidential, proprietary, and trade secret information, as described above, originated, in whole or in part, in the U.S. and was developed, in whole or in part, by Aptar's U.S. subsidiaries and divisions.

143. Defendants misappropriated Aptar's confidential, proprietary, and trade secret information when their employees acquired that information from [redacted], knowing (or, at a

minimum, having reason to know) that the trade secrets were acquired by improper means, in breach of [redacted] duty to Aptar to maintain the secrecy of that information.

144. Defendants also misappropriated Aptar's confidential, proprietary, and trade secret information when their employees disclosed and used the trade secrets without express or implied consent. At the time of the disclosure and use, Defendants knew or had reason to know that their knowledge of Aptar's trade secrets was derived from or through persons who owed a duty to Aptar to maintain the secrecy of the trade secret or limit the use of the trade secret. At a minimum, Defendants disclosed Aptar's trade secrets by circulating them internally. There is a threat that Defendants will further disclose and use Aptar's trade secrets in designing and executing IVBE studies. At least two of Defendants' employees who acquired Aptar's confidential, proprietary, and trade secret information from [redacted] work with Nemera's U.S.-based Insight Innovation Center on developing products in a related space.

145. Defendants intended to, and did, rely on Aptar's confidential, proprietary, and trade secret information to assist and accelerate their research and development of products and services, including their IVBE testing services, which are marketed and sold in the U.S. to U.S. customers. Further, those products and services are used in the design and development of products that have been or will be submitted for regulatory approval, marketed, and sold in the U.S. Upon information and belief, this work of research and development, marketing, and sales is carried out, in whole or in part, by the U.S.-headquartered Defendants. Defendants' acts of misappropriation, as described above, were taken in furtherance of these efforts.

146. As the direct and proximate result of Defendants' conduct, Aptar has suffered and, if Defendants' conduct is not stopped, will continue to suffer severe competitive harm, irreparable injury, and significant damages, in an amount to be proven at trial. Because Aptar's remedy at law is

inadequate, Aptar seeks, in addition to damages, injunctive relief to recover and protect its confidential, proprietary, and trade secret information and to protect other legitimate business interests. Aptar operates in a competitive market and will continue suffering irreparable harm absent injunctive relief.

147. Defendants' misappropriation of Aptar's confidential, proprietary, and trade secret information was willful and malicious.

148. Aptar has been damaged by all of the foregoing and is entitled to an award of exemplary damages and attorneys' fees.

JURY DEMAND

Aptar respectfully demands a trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Aptar respectfully requests the following relief:

a. an injunction ordering Defendants to (1) cease all unauthorized disclosure and use of any Aptar confidential information, (2) identify to Aptar all unauthorized recipients of Aptar confidential information, and (3) notify such unauthorized recipients to effect the return or destruction of all Aptar confidential information; and further (4) enjoining Defendants from obtaining any commercial benefit from their unlawful and unauthorized disclosure and use of Aptar confidential information;

b. judgment in Aptar's favor and against Defendants on all causes of action alleged herein;

c. damages in an amount to be further proven at trial, including but not limited to compensatory, punitive, and exemplary damages;

d. attorneys' fees and costs;

e. restitution;

f. prejudgment interest; and

g. any such other and further relief in equity or law as the Court may deem to be just and proper.

Date: February 16, 2021

Respectfully submitted,

/s/ Stephen A. Swedlow

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